Safety Data Sheet
acc. To OSHA HCS

Reviewed on 11 Apr 2022

Printing date 11 Apr 2022

Trade Name: ClearPEG™ 3350

1 Identification

1.1 Product identifier

Trade name: Polyethylene glycol 3350 granular
Product Code: C6005
Application of the substance / the mixture: Pharma Excipient

1.2 Details of the supplier of the safety data sheet
Manufacturer/Supplier:
SpecializedRx Products, LLC
7237 University Ave. NE
Fridley, MN 55432
www.specializedrx.com
sales@specializedrx.com

Information department:
Tel.: 1-888-512-1209
Fax: 1-612-424-8481

1.3 Emergency telephone number:
Emergency Telephone:
US: 1-888-512-1209
International: 1-888-512-1209

2 Hazard(s) identification

2.1 Classification of the substance or mixture
Material is not hazardous under the definition outlined in the Federal OSHA Hazard Communication Standard 29CFR 1910.1200.

2.2 Label elements
Hazard pictograms
N/A

Signal word N/A
Precautionary statements (GHS US) : N/A

2.3 Other hazards
Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

3 Composition/information on ingredients

Trade Name: ClearPEG™ 3350

3.1 Chemical Characterization: Substance
Description: CAS#: 25322-68-3

Component	CASRN	Concentration
Polyethylene glycol	25322-68-3	> 99.0 %

Common Name: polyethylene glycol 3350
Impurities and/or Stabilizing Additives: Not applicable

4 First-aid measures

4.1 Description of first aid measures
General information: No special measures required.
After inhalation: Remove from exposure and move to fresh air immediately. If symptoms appear, consult physician.
After skin contact: Wash off with plenty of water.
After eye contact: Rinse opened eye for several minutes under running water.
After swallowing: Emergency medical treatment unnecessary; consult physician if symptoms develop.

4.2 Most important symptoms and effects, both acute and delayed
See section 11; very low toxicity for ingestion and small amounts are unexpected to elicit harmful effects.

4.3 Indication of any immediate medical attention and special treatment needed
No relevant information available.

5 Fire-fighting measures

5.1 Extinguishing media
Suitable extinguishing agents: alcohol-resistant foam, carbon dioxide, water spray, sand. Use fire-fighting measures that suit the environment. **Do not use direct water stream; it may spread fire.**

5.2 Special hazards arising from the substance or mixture
Combustion of material will yield carbon monoxide & carbon dioxide; other combustion products of varying composition may also be produced, which may be toxic and/or irritating. Dust may present explosion hazard if allowed to suspend in air; dust may be ignited by static discharge.

5.3 Advice for firefighters
Protective equipment: In the event of fire, wear self-contained breathing apparatus. Avoid direct water streams directed at material as this may spread fire/force dust into atmosphere and create an explosion hazard. Burning liquids can be diluted with water.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:
Spilled material can create a slip hazard; clean up spills immediately.

6.2 Environmental precautions:
Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:
Collect into properly-labeled, suitable containers.

6.4 Reference to other sections
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

Protective Action Criteria for Chemicals
No relevant information available.

7 Handling and storage

7.1 Precautions for safe handling: No special precautions are necessary if used correctly.
Keep ignition sources away – do not smoke. Ground all equipment containing this material.

7.2 Conditions for safe storage, including any incompatibilities
Storage:
Requirements to be met by storerooms and receptacles: Avoid prolonged exposure to heat and air.
Information about storage in one common storage facility: Not required.
Further information about storage conditions: Avoid dust formation.

7.3 Specific end use(s): No further relevant information available.

8 Exposure controls/personal protection

Additional information about design of technical systems: No further data; see item 7.

8.1 Control parameters
Components with limit values that require monitoring at the workplace:

Control parameters
Exposure limits are listed below, if they exist.

Component	Regulation	Type of listing	Value/Notation
Polyethylene glycol	US WEEL	TWA aerosol	10 mg/m3

8.2 Exposure controls
Engineering controls: Use local exhaust ventilation to maintain airborne levels below exposure limits; if there are no applicable exposures, general ventilation should be sufficient for most operations.
Personal protective equipment:
Wear safety glasses with side-shields.
General protective and hygienic measures:
Wash hands before breaks and at the end of work.

Breathing equipment: Not required.
Protection of hands:
The glove material must be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation effects of the substance acting on the material.
Material of gloves:
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
Penetration time of glove material
The exact break through time must be found out by the manufacturer of the protective gloves and must be observed.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties
General Information
Appearance:
Form: Granules
Color: White
Odor: Mild
pH-value: 4.5 – 7.5 (5% aq solution)
Melting point/Melting range: 53 - 57°C (127 - 135°F)
Boiling point/Boiling range: > 200°C (>392°F) *Calculated*. Decomposes
Flash point: 246°C (475°F) **closed cup**
Flammability (solid, gaseous): Not applicable.
Ignition temperature: Not determined
Decomposition temperature: Not determined.
Auto igniting: Not determined
Danger of explosion: Not determined
Explosion limits:
Lower: Not determined
Upper: Not determined
Vapor pressure: < 0.01 mmHg @ 20°C (68°F)
Density: 1.0926 g/cm^3 @ 60°C (140°F) *Literature*
Relative density (water = 1): 1.111 @ 60°C (140°F) / 60°C *Calculated*
Relative Vapor density (air = 1): >10 *Calculated*
Evaporation rate: Not determined.
Solubility in / Miscibility with Water: 67% @ 20°C (68°F) *Measured*
Partition coefficient (n-octanol/water): Not determined.
Viscosity:
Dynamic: Not determined
Kinematic: 90.8 cSt @ 100°C (212°F)
Solvent content:
Organic solvents: 0.0 %
Water: 0.0 %
VOC content: 1 g/L *EPA Method No. 24*

9.2 Other information: No further relevant information available.

Trade Name: ClearPEG™ 3350

10 Stability and reactivity

10.1 Reactivity: Stable under normal conditions, avoid contact with strong acids, strong bases, and strong oxidizers.
10.2 Chemical stability: Stable under normal conditions, no hazardous reactions.
10.3 Possibility of hazardous reactions: Isolate from oxidizers, heat & open flame.
10.4 Conditions to avoid: Isolate from oxidizers and heat. Avoid static discharge.
10.5 Incompatible materials: Avoid contact with strong acids, strong bases, and strong oxidizers.
10.6 Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

11.1 Information on toxicological effects
Acute toxicity:

LD/LC50 values that are relevant for classification:		
Oral	LD50	>10,000 mg/kg (rat) Estimated
Dermal	LD50	>20,000 mg/kg (rabbit)
Inhalation	LC50	>2.5 mg/L (rat, 6hr exposure, dust/mist); no deaths at this concentration

Primary irritant effect:
on the skin: Unlikely to affect healthy skin; prolonged/repeated exposure of damaged skin (i.e., as with burn patients) may result in sufficient absorption to reach toxic amounts.
on the eye: May result in slight temporary eye irritation; corneal injury is unlikely
Sensitization: Not a known sensitizer/no known sensitizing effects known.
Additional toxicological information:
Carcinogenic categories
IARC (International Agency for Research on Cancer): Substance not listed.
NTP (National Toxicology Program): Substance is not listed.
OSHA-Ca (Occupational Safety & Health Administration): Substance is not listed.

12 Ecological information

12.1 Toxicity
Aquatic toxicity:
Acute Toxicity to fish:
Material is practically non-toxic to aquatic organisms on an acute basis (LC50/EC50/EL50/LL50 >100 mg/L in the most sensitive species tested).
LC50, Pimephales promelas (fathead minnow), 96 Hour, 58,900 mg/l
Acute Toxicity to aquatic invertebrates:
EC50, Daphnia magna (Water flea), 48 Hour, 22,100 mg/l
Toxicity to bacteria:
EC50, Bacteria, 16 Hour, > 10,000 mg/l

12.2 Persistence and degradability:
Biodegradability: Material is readily biodegradable. Passes OECD test(s) for ready biodegradability.
10-day Window: Pass
Biodegradation: 90 %
Exposure time: 28 d
Method: OECD Test Guideline 301B or Equivalent

Chemical Oxygen Demand: 1.81 mg/mg
Biological oxygen demand (BOD)

Incubation Time	BOD
5 d	5 %
10 d	5 %
20 d	11 - 23 %

12.3 Bioaccumulative potential:
Bioaccumulation: No bioconcentration is expected because of the relatively high-water solubility.
12.4 Mobility in soil: No further relevant information available.

Additional ecological information:
General notes:
Do not allow product it to reach ground water, water course or sewage system.

12.5 Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

12.6 Other adverse effects: No further relevant information available.

13 Disposal considerations

13.1 Waste treatment methods
Recommendation: Do not dump product directly on ground, into sewers or into any body of water. If product is to be incinerated, beware of dust formation as it is an explosion hazard..
Uncleaned packaging:
Recommendation: Disposal must be made according to official regulations.
Recommended cleansing agent: No relevant information available.

14 Transport information

14.1 UN-Number	
DOT, ADR, ADN, IMDG, IATA	Not regulated for transport
14.2 UN proper shipping name	
DOT, ADR, ADN, IMDG, IATA	Not regulated for transport
14.3 Transport hazard class(es)	
DOT, ADR, ADN, IMDG, IATA	
Class	Not regulated for transport
14.4 Packing group	
DOT, ADR, IMDG, IATA	Not regulated for transport
14.5 Environmental hazards:	Not applicable.
14.6 Special precautions for user	Not applicable.
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

Trade Name: ClearPEG™ 3350

UN "Model Regulation":	Void

15 Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
· **Sara Section 355 (extremely hazardous substances):** Substance is not listed.
· **Sara Section 313 (Specific toxic chemical listings):** Substance is listed.
· **TSCA (Toxic Substances Control Act):** ACTIVE
· **Hazardous Air Pollutants** Substance is not listed.
· **Proposition 65**
· **Chemicals known to cause cancer:** Substance is not listed.
· **Chemicals known to cause reproductive toxicity for females:** Substance is not listed.
· **Chemicals known to cause reproductive toxicity for males:** Substance is not listed

16 Other information

This SDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

Department issuing SDS:
SpecializedRx Products, LLC
Quality Assurance
Contact: sales@specializedrx.com
Date of preparation / last revision: 11 Apr 2022

Abbreviations and acronyms:
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit